K113567

SYNTHES®

510(k) Summary

Date Prepared	November 15, 2012
Submitter	Synthes (USA) 1301 Goshen Parkway West Chester, PA 19380 United States of America
Contact	Alan T. Haley haley.alan@synthes.com (484) 356-9763
Trade Name	MatrixMANDIBLE Plate and Screw System
Common Name	Bone Plate
Classification Name	Bone Plate, 21 CFR 872.4760, Product Code JEY
Predicate Devices	MatrixMANDIBLE Plate and Screw System (K063790) Synthes 2.0 mm Locking Plate System (K974555)

NOV 19 2012

Intended Use

The Synthes MatrixMANDIBLE plate and screw system is intended for oral, maxillofacial surgery:

- Trauma
- Reconstructive surgery
- Orthognathic surgery (surgical correction of dentofacial deformities)

Device Description

The Synthes MatrixMANDIBLE Plate and Screw System consists of a variety of plates offered in multiple shapes and sizes and a variety of screws offered in multiple diameters and lengths to meet the anatomical needs of the patient.

This submission pertains to 1.5 mm thick MatrixMANDIBLE Reconstruction Plates, which are available as left and right single angle reconstruction plates and in three sizes of double angle reconstruction plates. These plates are made from pure titanium and may be offered sterile or non-sterile (non-sterile implants must be sterilized prior to use).

MatrixMANDIBLE 1.5 mm thick reconstruction plates are intended for single use only.

Comparison to Predicate Devices

Indications for Use

The Indications for Use statement for the proposed device is identical to the Indications for Use statement for the Synthes MatrixMANDIBLE Plate and Screw System predicate (K063790).

The Indications for Use statement for the proposed device is similar to the Indications for Use statement for the Synthes 2.0 mm Locking Plate System predicate (K974555). Both statements include oral, maxillofacial surgery, trauma, reconstructive surgery, and surgical correction of dentofacial deformities.

The differences in the Indications statement for the proposed device in comparison to the predicates do not constitute a new intended use.

Technological Similarities

- The proposed device has the same principles of operation (metallic plate used for the internal fixation of mandibular bone) as the predicate devices.
- The proposed device is offered in single angle (right and left) and double angle (three sizes) configurations; the predicate devices are offered in the same configurations.
- The double angle configurations of the proposed device have the same number of holes as the double angle configurations of the predicate devices.
- The single angle configurations of the proposed device have the same number of holes as the single angle configurations of the Synthes MatrixMANDIBLE Plate and Screw System predicate (K063790).
- The proposed device is made of the same material (titanium) as the predicate devices.
- The thickness of the proposed device is within the range of thicknesses as the predicate devices.
- The proposed device and the predicate devices have threaded static locking screw holes.
- The proposed device is compatible with the same MatrixMANDIBLE screws as the Synthes MatrixMANDIBLE Plate and Screw System predicate (K063790).

Technological Differences

- The width of the proposed devices is slightly greater than the width of the predicate devices.
- In addition to the single and double angle configurations, the predicate devices are offered in a straight (no angle) configuration. The proposed device is not offered in a straight configuration.
- The single angle configurations of the proposed device have one more hole and are slightly longer than the single angle configurations of the Synthes 2.0 mm Locking Plate System predicate (K974555).

Non-Clinical Performance Data

An engineering assessment, including a cross section analysis and finite element analysis, was used to compare the 1.5 mm thick MatrixMANDIBLE Reconstruction Plates to the predicate devices. The analysis determined that the in-plane and out-of-plane mechanical properties of the 1.5 mm thick MatrixMANDIBLE Reconstruction Plates are comparable to the in-plane and out-of-plane mechanical properties for the predicate Synthes 2.0 mm Locking Plate System (K974555).

Clinical Performance Data

No clinical testing was performed to support this submission.

Substantial Equivalence

The proposed devices have the same intended use as the predicate devices. The non-clinical performance data included in this submission demonstrate that the proposed devices are as safe, as effective, and perform as well as or better than the predicate devices. It is concluded that the information included in this submission supports substantial equivalence.

(end of summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 19, 2012

Mr. Alan T. Haley
Regulatory Affairs Specialist
Synthes® Incorporated
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K113567
Trade/Device Name: MatrixMANDIBLE Plate and Screw System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: November 9, 2012
Received: November 13, 2012

Dear Mr. Haley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K113567

SYNTHES®

4 Indications for Use Statement

510(k) Number (if known): K113567

Device Name: MatrixMANDIBLE Plate and Screw System

Indications for Use: The Synthes MatrixMANDIBLE plate and screw system is intended for oral, maxillofacial surgery:

- Trauma
- Reconstructive surgery
- Orthognathic surgery (surgical correction of dentofacial deformities)

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner

Digitally signed by Mary S. Runner
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner, 0.9.2342.19200300.100.1.1=13000879S0
Date: 2012.11.19 10:09:23 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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